

1996 No. 967

## HEALTH AND SAFETY

The Genetically Modified Organisms (Contained Use)  
(Amendment) Regulations 1996

Made	- - -	27th March 1996
Laid before Parliament		3rd April 1996
Coming into force		27th April 1996

The Secretary of State, being the Minister designated(a) under section 2(2) of the European Communities Act 1972(b) in relation to the control and regulation of genetically modified organisms and in the exercise of the powers conferred on him by the said section 2(2) and sections 15(1), (2), (4)(a) and (5)(a) of, and paragraphs 1(1)(b) and (c) and (5), 4(1) and 15(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(c) ("the 1974 Act") and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of the 1974 Act, hereby makes the following Regulations—

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 and shall come into force on 27th April 1996.

(2) In these Regulations, "the principal Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 1992(d).

**Amendments to the principal Regulations**

2.—(1) The principal Regulations shall be amended in accordance with Schedule 1 to these Regulations.

(2) The Schedule set out in Schedule 2 to these Regulations shall be substituted for Schedule 2 to the principal Regulations.

27th March 1996

John Selwyn Gummer  
Secretary of State,  
Department of the Environment.

(a) S.I. 1991/775.

(b) 1972 c. 68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c. 51).

(c) 1974 c. 37; sections 15(1) and 50(3) were amended by the Employment Protection Act 1975 (1975 c. 71), Schedule 15, paragraphs 6 and 16(3) respectively.

(d) S.I. 1992/3217, extended to include the States of the European Economic Area by virtue of section 2(1) of the European Economic Area Act 1993 (c. 51).

[DOE 0623]



## AMENDMENTS TO THE PRINCIPAL REGULATIONS

1. The regulations of the principal Regulations shall be amended in accordance with the following paragraphs of this Schedule.

2. In Regulation 2—

(a) in paragraph (1)—

- (i) after the definition of “activity involving genetic modification” insert the following definition—  
“ “the Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993 and adopted as respects the United Kingdom by the European Economic Area Act 1993(a);”,
- (ii) after the definition of “the contained use Directive” insert the following definition—  
“ “the European Economic Area” means the Area referred to in the Agreement;”,
- (iii) after the definition of “genetic modification safety committee” insert the following definition—  
“ “member State” means a State which is a Contracting Party to the Agreement;”,  
and
- (iv) for the definition of “organism” substitute the following definition—  
“ “organism” means a biological entity capable of replication or transferring genetic material and includes a micro-organism, but does not include a human or a human embryo;”; and

(b) for paragraph (2), substitute the following paragraph—

“(2) Genetically modified organisms shall be classified—

(a) in the case of micro-organisms—

- (i) as Group I micro-organisms if they satisfy all of the criteria set out in Part I of Schedule 2, or
- (ii) as Group II micro-organisms if they do not satisfy all of the said criteria;  
or

(b) in the case of genetically modified organisms other than micro-organisms, as satisfying the criteria set out in Part II of Schedule 2 if they so satisfy those criteria.”.

3. For sub-paragraph (a) of paragraph (2) of regulation 6 substitute the following sub-paragraph—

“(a) genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of, where such organisms are or are contained in—

(i) a product marketed in pursuance of either—

(aa) a consent granted by the Secretary of State under section 111(1) of the Environment Protection Act 1990(b); or

(bb) a written consent given by another competent authority of a member State in accordance with Article 13(4) of Council Directive 90/220/EEC(c) on the deliberate release into the environment of genetically modified organisms;

and in either case, the operation is conducted in accordance with any conditions or limitations attached to that consent, or

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No. 2309/93(d); and”.

(a) 1993 c. 51.

(b) 1990 c. 43.

(c) O.J. No. L117, 8.5.90, p. 15.

(d) O.J. No. L214, 24.8.93, p. 1.



4. At the end of paragraph (2) of regulation 8 but before the full stop, insert a comma followed by the words—

“except that a separate notification shall not be required—

- (a) where a consent has already been given under paragraph (3) for activities involving Group II micro-organisms and the premises are to be used for activities involving Group I micro-organisms; or
- (b) where simultaneous notification is being given of an intention to use premises for activities involving both Group I and Group II micro-organisms”.

5. In sub-paragraphs (2)(b) and (4)(b) of regulation 9 for the words “Part III” in each place where they occur substitute the words “Part II”.

6. In regulation 16—

- (a) delete the word “and” at the end of sub-paragraph (4)(a); and
- (b) for sub-paragraph (4)(b) substitute the following sub-paragraph—  
“(b) Rose Court, 2 Southwark Bridge, London, SE1 9HS; and”.

7. In paragraph 3(e) of Schedule 1 for the words “fulfil the criteria of Part III” substitute the words “satisfy the criteria of Part II”.

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## SCHEDULE 2

Regulation 2(2)

### SCHEDULE TO BE SUBSTITUTED AS SCHEDULE 2 TO THE PRINCIPAL REGULATIONS

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## SCHEDULE 2

Regulation 2(2)

### CRITERIA FOR THE CLASSIFICATION OF ORGANISMS

#### PART I

##### **Criteria for the classification of genetically modified organisms into Group I**

A genetically modified micro-organism is classified into Group I when all of the following criteria are satisfied—

- (1) The recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants.
- (2) The nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause adverse effects in the environment.
- (3) The genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to cause adverse effects in the environment.

#### PART II

##### **Criteria for the classification of organisms other than micro-organisms**

An organism which satisfies the criteria of this Part is a genetically modified organism—

- (a) which is not a micro-organism; and
- (b) which is as safe in the containment facility as any recipient or parental organism.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 1992 (S.I. 1992/3217) ("the principal Regulations") in the following ways—

### Paragraph 2(a) of Schedule 1

1. Council Directive 90/219/EEC (OJ No. L117, 8.5.90, p.1), on the contained use of genetically modified micro-organisms, implemented by the principal Regulations, now applies to the States of the European Economic Area by virtue of the Agreement on the European Economic Area. A definition of "member State", which includes those States, is, therefore, inserted into regulation 2(1) of the principal Regulations. Definitions of "the European Economic Area" and "the Agreement" are also inserted into that regulation.

2. The definition of "organism" in regulation 2(1) of the principal Regulations is amended to exclude humans and human embryos, which are outside the scope of the above Directive.

### Paragraphs 2(b), 5 and 7 of Schedule 1; Schedule 2

3. Regulation 2(2) and Schedule 2 of the principal Regulations are replaced, to implement the new classification criteria for micro-organisms contained in Commission Directive 94/51/EC (OJ No. L297, 18.11.94, p.29), which adapts to technical progress Council Directive 90/219/EEC. There are minor consequential amendments to regulation 9 of, and paragraph 3(e) of Schedule 1 to, the principal Regulations.

### Paragraph 3 of Schedule 1

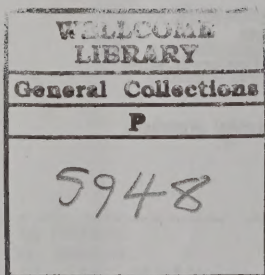
4. By Article 5 of Council Directive 90/219/EEC, genetically modified micro-organisms marketed in accordance with other Community legislation providing equivalent risk assessment to that required under the said Directive, are excluded from the scope of that Directive as regards storage, transport, destruction and disposal. The exemptions contained in regulation 6(2)(a) of the principal Regulations are extended to exclude from the prohibitions in regulation 6(1) certain medicinal products marketed in accordance with Council Regulation (EEC) No. 2309/93 (OJ No. L214, 24.8.93, p.1).

### Paragraph 4 of Schedule 1

5. Regulation 8(2) of the principal Regulations is amended to provide that a separate notification is not required where a consent for Group II micro-organisms has already been granted and it is intended to use the premises for activities involving Group I micro-organisms, or where simultaneous notification is being given for activities involving Group I and II micro-organisms at the same premises.

### Paragraph 6 of Schedule 1

6. Regulation 16(4)(b) of the principal Regulations, specifying the location where a copy of the register of notifications is held, is amended to specify the current address for the Health and Safety Executive in London.



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